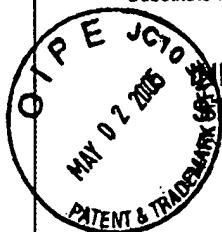


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INFORMATION DISCLOSURE  
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Sheet 1 of 15

## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
AB		4,116,589		Rishton	09-26-1978	
		4,189,470		Rose	02-19-1980	
		4,191,182		Popovich, et al.	03-04-1980	
		4,350,156		Malchesky, et al.	09-21-1982	
		4,362,155		Skurkovich	12-07-1982	
		4,375,414		Strahilevitz	03-01-1983	
		4,581,010		Skurkovich, et al.	04-08-1986	
		4,605,394		Skurkovich	08-12-1986	
		4,620,977		Strahilevitz	11-04-1986	
		4,633,417		Wilburn, et al.	12-30-1986	
		4,634,417		Korec	01-06-1987	
		4,664,913		Mielke, et al.	05-12-1987	
		4,801,449		Balint, Jr., et al.	01-31-1989	
AB		4,813,924		Strahilevitz	03-21-1989	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
AB	✓	DE	3302384		Lysaght, et al.	01-25-1983		AB
	✓	EP	0076665		E.I. Du Pont De Nemours	01-14-1987		✓
	✓	GB	2136314		Gelman Sciences, Inc.	09-19-1984		✓
	✓	JP	56092824		Terumo Corporation	07-27-1981		AB
AB	✓	PCT	WO 79/01121		The Government of the United States of America	12-27-1979		

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*ReBianco*

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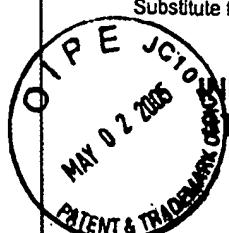
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Sheet 2 of 15

## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		4,824,432		Skurkovich, et al.	04-25-1989	
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		5,037,645		Strahilevitz	08-06-1991	
		5,037,649		Balint, Jr., et al.	08-06-1991	
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		5,356,374		Hogan, et al.	10-18-1994	
		5,605,690		Jacobs, et al.	02-25-1997	
		5,626,843		Skurkovich, et al.	05-06-1997	
		5,643,732		Strahilevitz	07-01-1997	
		5,705,615		Lim, et al.	01-06-1998	
		5,730,713		Okarma, et al.	03-24-1998	
		5,753,227		Strahilevitz	05-19-1998	
		5,840,588		Strahilevitz	11-24-1998	
		5,869,047		Blake	02-09-1999	
		5,888,511		Skurkovich, et al.	03-30-1999	
		5,910,252		Truitt, et al.	06-08-1999	
		6,039,946		Strahilevitz	03-21-2000	
		6,197,289		Wirt, et al.	03-06-2001	
		6,221,614		Prusiner, et al.	04-24-2001	
		6,245,038		Borberg, et al.	06-12-2001	
		6,264,623		Strahilevitz	07-24-2001	
		6,287,516		Matson, et al.	09-11-2001	
		6,428,790		Boyd	08-06-2002	
		6,432,405		Weinberg, et al.	08-13-2002	
		6,528,057		Ambrus, et al.	03-04-2003	

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Signature*P. Bianco*

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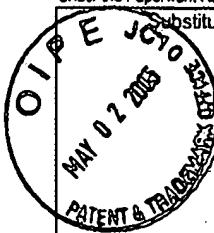
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## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## U.S. PATENT DOCUMENTS

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		Number	Kind Code <sup>2</sup> (if known)			
AB		6,561,997		Weitzel, et al.	05-13-2003	
		6,569,112		Strahilevitz	05-27-2003	
		6,602,502		Strahilevitz	08-05-2003	
		6,602,993		Wallach, et al.	08-05-2003	
		6,607,501		Gorsuch	08-19-2003	
		6,607,723		Good, et al.	08-19-2003	
		6,627,151		Borberg, et al.	09-30-2003	
		6,630,315		Miwa, et al.	10-07-2003	
		6,676,622		Strahilevitz	01-13-2004	
		6,685,664		Levin, et al.	02-03-2004	
		RE 31,688		Popovich, et al.	09-25-1984	
		RE 36,755		Smith, et al.	06-27-2000	
		2001/0010818		Engle, et al.	08-02-2001	
		2001/0039392		Strahilevitz	11-08-2001	
		2002/0019603		Strahilevitz	02-14-2002	
		2002/0058031		Tung, et al.	05-16-2002	
		2002/0086276		Srivastava	07-04-2002	
		2002/0107469		Bolan, et al.	08-08-2002	
		2002/0111577		Sirimanne, et al.	08-15-2002	
		2002/0119147		Howell, et al.	08-29-2002	
		2002/0159995		Brady, et al.	10-31-2002	
		2002/0183677		Chang, et al.	12-05-2002	
		2002/0187069		Levin, et al.	12-12-2002	
		2002/0197249		Brady, et al.	12-26-2002	
		2002/0197250		Brady, et al.	12-26-2002	
		2002/0197251		Brady, et al.	12-26-2002	
AB		2003/0073822		Lofling, et al.	04-17-2003	
		2003/0118584		Glenn, et al.	06-26-2003	

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 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number 09/699,003 Filing Date October 26, 2000 First Named Inventor M. Riggdon Lentz Group Art Unit 3762 Examiner Name P. Blanco Attorney Docket Number LEN 101 CIP CON	
Sheet	4	of	15

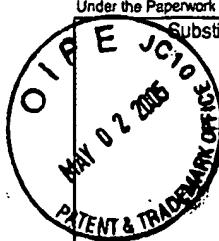
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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet

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of

15

## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Blanco
Attorney Docket Number	LEN 101 CIP CON

OTHER ART - NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
PLB	✓	ABBRUZZESE, et al., "A phase II trial of recombinant human interferon-gamma and recombinant tumor necrosis factor in patients with advanced gastrointestinal malignancies: Results of a trial terminated by excessive toxicity" <i>Journal of Biological Response Modifiers</i> 9:522-527 (1990).
	✓	ADOLF AND APFLER, "A monoclonal antibody-based enzyme immunoassay for quantitation of human tumor necrosis factor binding protein I, a soluble fragment of the 60kDa TNF receptor, in biological fluids" <i>J. Immunol. Meth.</i> 143:127-136 (1991).
	✓	AJANI, et al., "Phase I and II studies of the combination of recombinant human interferon-γ and 5-fluorouracil in patients with advanced colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 8:140-146 (1989).
	✓	ALBERTINI, et al., "Limiting dilution analysis of lymphokine-activated killer cell precursor frequencies in peripheral blood lymphocytes of cancer patients receiving interleukin-2 therapy" <i>Journal of Biological Response Modifiers</i> 9:456-462 (1990).
	✓	ARENDE, "Inhibiting the effects of cytokines in human diseases" <i>Adv. Int. Med.</i> 40:365-394 (1995).
	✓	AVNER, et al., "Therapeutic murine monoclonal antibodies developed for individual cancer patients" <i>Journal of Biological Response Modifiers</i> 8:25-36 (1989).
	✓	BALCEWICZ-SABLINSKA, et al., "Pathogenic <i>Mycobacterium tuberculosis</i> evades apoptosis of host macrophages by release of TNF-R2, resulting in inactivation of TNF-α" <i>J. Immunol.</i> 161:2636-2641 (1998).
	✓	BALIKO, et al., "Th2 biased immune response in cases with active <i>Mycobacterium tuberculosis</i> infection and tuberculin anergy" <i>FEMS Immunol. Med. Micro.</i> 22:188-204 (1998).
PLB	✓	BERMUDEZ AND CHAMPSI, "Infection with <i>Mycobacterium avium</i> induces production of interleukin-10 (IL-10), and administration of anti-IL-10 antibody is associated with enhanced resistance to infection in mice" <i>Infect. Immun.</i> 61:3093-3097 (1993).
PLB	✓	BEUTLER AND CERAMI, "The biology of cachectin/TNF-A primary mediator of the host response" <i>Ann. Rev. Immunol.</i> 7:625-655 (1989).

Examiner's Signature	<i>PLB</i>	Date Considered	9/20/05
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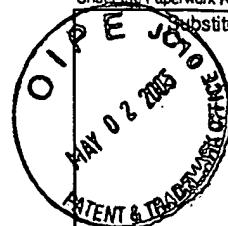
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Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Riggan Lentz
Group Art Unit	3761
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
RLB	✓	BLAUER, et al., "Modulation of the antilisterial activity of human blood-derived macrophages by activating and deactivating cytokines" <i>J. Interferon Cytokine Res.</i> 15:105-114 (1995).	
	✓	BOMAN, et al., "Phase I study of recombinant gamma-interferon (rIFN- $\gamma$ )" <i>Journal of Biological Response Modifiers</i> 7:438-446 (1988).	
	✓	BRUNTSCH, et al., "phase II study of recombinant human interferon- $\gamma$ in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:335-338 (1990).	
	✓	BUKOWSKI, et al., "Phase I trial of continuous infusion of recombinant interleukin-2 and intermittent recombinant interferon- $\alpha_{2a}$ . Clinical effects" <i>Journal of Biological Response Modifiers</i> 9:538-545 (1990).	
	✓	CAULFIELD, et al., "Phase I1-Ib trial of an anti-G <sub>0</sub> monoclonal antibody in combination with interferon- $\alpha$ in patients with malignant melanoma" <i>Journal of Biological Response Modifiers</i> 9:319-328 (1990).	
	✓	CHAMBRIER, et al., "Hormonal and metabolic effects of chronic interleukin-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:251-255 (1990).	
	✓	CHOUAIB, et al., "More insights into the complex physiology of TNF" <i>Immunol. Today</i> 12(5):141-145 (1991).	
	✓	COCLET-NININ, et al., "Interferon-beta not only inhibits interleukin-1 $\beta$ and tumor necrosis factor- $\alpha$ but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononuclear cells" <i>Eur. Cytokine Network</i> 8(4):345-349 (1997).	
	✓	COLMAN, et al., <i>Hemostasis and Thrombosis: Basic Principles and Clinical Practice</i> 2nd. Edition (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, PA, 1987.	
	✓	COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple myeloma" <i>Journal of Biological Response Modifiers</i> 7:318-325 (1988).	
RLB	✓	CREAVEN, et al., "Initial clinical trial of the macrophage activator muramyl tripeptide-phosphatidylethanolamine encapsulated in liposomes in patients with advanced cancer" <i>Journal of Biological Response Modifiers</i> 9:492-498 (1990).	

Examiner's Signature	<i>RLB</i>	Date Considered	9/20/05
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Sheet 7 of 15

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Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Riggdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

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PLB	✓	CROGHAN, et al., "A phase I trial of recombinant interferon- $\alpha$ and $\alpha$ -difluoromethylornithine in metastatic melanoma" <i>Journal of Biological Response Modifiers</i> 7:409-415 (1988).	
	✓	D'ANDREA, et al., "Interleukin 10 (IL-10) inhibits human lymphocyte interferon $\gamma$ production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells" <i>J. Exp. Med.</i> 178:1041-1048 (1993).	
	✓	DIMERY, et al., "Recombinant interferon- $\gamma$ in the treatment of recurrent nasopharyngeal carcinoma" <i>Journal of Biological Response Modifiers</i> 8:221-226 (1989).	
	✓	DINARELLO, "Induction of interleukin-1 and interleukin-1 receptor antagonist" <i>Sem. In Oncol.</i> 24(no. 3, Suppl. 9):81-93 (1997).	
	✓	DUPERE, et al., "Patterns of cytokines released by peripheral blood leukocytes of normal donors and cancer patients during interleukin-2 activation <i>in vitro</i> " <i>Journal of Biological Response Modifiers</i> 9:140-148 (1990).	
	✓	ENGELHARDT, et al., "Biological response to intravenously administered endotoxin in patients with advanced cancer" <i>Journal of Biological Response Modifiers</i> 9:480-491 (1990)	
	✓	ENGELMANN, et al., "Two tumor necrosis factor-binding proteins purified from human urine" <i>J. Biol. Chem.</i> 265(3):1531-1536 (1990).	
	✓	ERIKS AND EMERSON, "Temporal effect of tumor necrosis factor alpha on murine macrophages infected with <i>Mycobacterium avium</i> " <i>Infect. Immun.</i> 65(6):2100-2106 (1997).	
	✓	ETGES AND MULLER, "Progressive disease or protective immunity to <i>Leishmania</i> major infection: the result of a network of stimulatory and inhibitory interactions" <i>J. Mol. Med.</i> 76:372-390 (1998).	
	✓	FAREED, et al., "Novel antigenic markers of human tumor regression" <i>Journal of Biological Response Modifiers</i> 7:11-23 (1988).	
PLB		FAVROT, et al., "Functional and immunophenotypic modifications induced by interleukin-2 did not predict response to therapy in patients with renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:167-177 (1990).	

Examiner's Signature PLB Date Considered 9/10/05

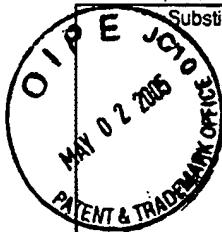
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## Complete If Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3763
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
DLB	✓	FERNANDES AND BALDWIN, "Interleukin-10 downregulates protective immunity to <i>Brucella abortus</i> " <i>Infect. Immun.</i> 63:1130-1133 (1995).	
	✓	FOON, et al., "A prospective randomized trial of $\alpha_{2b}$ -interferon/ $\gamma$ -interferon or the combination in advanced metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 7:540-545 (1988).	
	✓	FROST, et al., "Interleukin-6 induction by a muramyltripeptide derivative in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:160-166 (1990).	
	✓	GADDUCCI, et al., "Serum levels of soluble receptors for tumor necrosis factor (p55 and p75 sTNFr) in endometrial cancer" <i>Anticancer Res.</i> 16:3125-3128 (1996).	
	✓	GILL, et al., "Interferon-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunodeficiency syndrome-related kaposi's sarcoma" <i>Journal of Biological Response Modifiers</i> 9:512-516 (1990).	
	✓	GREENBLATT, et al., "The type B receptor for tumor necrosis factor-alpha" <i>Blood</i> 80:1339-1346 (1992).	
	✓	GUSTAVSON, et al., "Pharmacokinetics of teceleukin (Recombinant human interleukin-2) after intravenous or subcutaneous administration to patients with cancer" <i>Journal of Biological Response Modifiers</i> 8:440-449 (1989).	
	✓	HANDZEL, et al., "Immunomodulation of T cell deficiency in humans by thymic humoral factor: from crude extract to synthetic thymic humoral factor- $\gamma$ 2" <i>Journal of Biological Response Modifiers</i> 9:269-278 (1990).	
DLB	✓	HANK, et al., "Depressed <i>in vitro</i> T cell responses concomitant with augmented interleukin-2 responses by lymphocytes from cancer patients following <i>in vivo</i> treatment with interleukin-2" <i>Journal of Biological Response Modifiers</i> 9:5-14 (1990).	
DLB	✓	HERCEND, et al., "Immunotherapy with lymphokine-activated natural killer cells and recombinant interleukin-2: A feasibility trial in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:546-555 (1990).	

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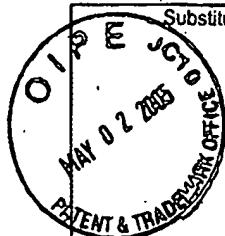
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Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Riggdon Lentz
Group Art Unit	3762
Examiner Name	P. Blanco
Attorney Docket Number	LEN 101 CIP CON

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Sheet 10 of 15

## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

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PLB	✓	KOLITZ, et al., "Phase I trial of recombinant interleukin-2 and cyclophosphamide: Augmentation of cellular immunity and T-cell mitogenic response with long term administration of rIL-2" <i>Journal of Biological Response Modifiers</i> 7:457-472 (1988).	
	✓	KRIGEL, et al., "Treatment of epidemic kaposi's sarcoma with a combination of interferon-alpha 2b and etoposide" <i>Journal of Biological Response Modifiers</i> 7:359-364 (1988).	
	✓	LANTZ, et al., "Infusion of tumor necrosis factor (TNF) causes an increase in circulating TNF-binding protein in humans" <i>Cytokine</i> 2(6):402-406 (1990).	
PLB	✓	LASZLO, et al., "Phase I studies of recombinant interferon- $\gamma$ " <i>Journal of Biological Response Modifiers</i> 9:185-193 (1990).	
		LAUCELLA, et al., "Papel de las citoquinas en la resistencia y patología durante la infección con <i>Trypanosoma cruzi</i> " <i>Revista Argentina de Microbiología</i> , 28:99-109 (1996). <span style="float: right;">N</span>	
PLB	✓	LENTZ, et al., "Apheresis of low molecular weight protein fraction and the onset of labor" <i>Journal of Clinical Apheresis</i> 5:62-67 (1990).	
	✓	LENTZ, "The phylogeny of oncology" <i>Mol. Biother.</i> 2:137-144 (1990).	
	✓	LETTERIO AND ROBERTS, "Regulation of immune responses by TGF- $\beta$ " <i>Ann. Rev. Immuno.</i> 16:137-161 (1998).	
	✓	LITTON, et al., "Biological and clinical effects of the oral immunomodulator 3,6'Bis(2-piperidinoethoxy)acridine trihydrochloride in patients with malignancy" <i>Journal of Biological Response Modifiers</i> 9:61-70 (1990).	
	✓	LUCEY, et al., "Type 1 and type 2 cytokine dysregulation in human infectious, neoplastic, and inflammatory diseases" <i>Clin. Micro. Rev.</i> 9(4):532-562 (1996).	
PLB	✓	MAAS, et al., "Interleukin-2 in cancer treatment: disappointing or (still) promising? A review" <i>Cancer Immunol. Immunother.</i> 36:141-148 (1993).	

Examiner's Signature	<i>Bianco</i>	Date Considered	9/20/05
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Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3762
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

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AB	✓	MACA, "Inhibition of the growth of lewis lung carcinoma by indomethacin in conventional , nude, and beige mice" <i>Journal of Biological Response Modifiers</i> 9:568-580 (1990).	
	✓	MARSHALL, et al., "Effects of coumarin (12-benzopyrone) and cimetidine on peripheral blood lymphocytes, natural killer cells, and monocytes in patients with advanced malignancies" <i>Journal of Biological Response Modifiers</i> 8:62-69 (1989).	
	✓	MARSHALL, et al., "Treatment of renal cell carcinoma with daily low-dose alpha-interferon" <i>Journal of Biological Response Modifiers</i> 8:453-461 (1989).	
	✓	MILES, et al., "induction of soluble tumour necrosis factor receptors during treatment with Interleukin-2" <i>Brit. J. Cancer</i> 66:1195-1199 (1992).	
	✓	MITTELMAN, et al., "Treatment of patients with advanced cancer using multiple long-term cultured lymphokine-activated killer (LAK) cell infusions and recombinant human interleukin-2" <i>Journal of Biological Response Modifiers</i> 8:468-478 (1989).	
	✓	MUSIANI, et al., "Effect of low doses of interleukin-2 injected perilymphatically and peritumorally in patients with advanced primary head and neck squamous cell carcinoma" <i>Journal of Biological Response Modifiers</i> 8:571-578 (1989).	
	✓	NEIDHART, "Phase I study of recombinant methionyl human consensus interferon (r-methHIFN-Con)" <i>Journal of Biological Response Modifiers</i> 7:240-248 (1988).	
	✓	ORATZ, et al. "Induction of tumor-infiltrating lymphocytes in human malignant melanoma metastases by immunization to melanoma antigen vaccine" <i>Journal of Biological Response Modifiers</i> 8:355-358 (1989).	
	✓	ORATZ, et al., "Antimelanoma monoclonal antibody-ricin A chain immunoconjugate (XMMME-001-RTA) plus cyclophosphamide in the treatment of metastatic malignant melanoma: Results of a phase II trial" <i>Journal of Biological Response Modifiers</i> 9:345-354 (1990).	
ABM	✓	PAIS, et al., "Pharmacokinetics of recombinant interleukin-2 in children with malignancies: A pediatric oncology group study" <i>Journal of Biological Response Modifiers</i> 9:517-521 (1990).	

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Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Riggan Lentz
Group Art Unit	3762
Examiner Name	P. Blanco
Attorney Docket Number	LEN 101 CIP CON

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

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Alb	✓	PAOLOZZI, et al., "Phase I trial of recombinant interleukin-2 and recombinant $\beta$ -interferon in refractory neoplastic diseases" <i>Journal of Biological Response Modifiers</i> 8:122-139 (1989).	
	✓	PEREZ, et al., "A phase I trial of recombinant human gamma interferon (IFN- $\gamma$ A) in patients with advanced malignancy" <i>Journal of Biological Response Modifiers</i> 7:309-317 (1988).	
	✓	QUESADA, et al., "Recombinant interferon alpha and gamma in combination as treatment for metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 7:234-239 (1988).	
	✓	RABINOWITZ, et al., "Hemolytic anemia in a cancer patient treated with recombinant interferon- $\gamma$ " <i>Journal of Biological Response Modifiers</i> 9:256-259 (1990).	
	✓	REIMANN, et al., "Suppression of the immune response by micro-organisms" <i>Scand. J. Immunol.</i> 31:543-546 (1990).	
	✓	RIFFKIN, et al., "Defense against the immune barrage: helminth survival strategies" <i>Immunol. Cell Bio</i> 74:564-574 (1996)	
	✓	ROMANI, et al., "T helper cell dichotomy to <i>Candida albicans</i> : implications for pathology" <i>Immunol. Res.</i> 14:148-162 (1995).	
	✓	ROSENTHAL, et al., "The <i>in vitro</i> function of lymphocytes from 25 cancer patients receiving four to seven consecutive days of recombinant IL-2" <i>Journal of Biological Response Modifiers</i> 7:123-139 (1988).	
	✓	RYBAK, et al., "Interferon therapy of relapsed and refractory hodgkin's disease: Cancer and leukemia group B study 8652" <i>Journal of Biological Response Modifiers</i> 9:1-4 (1990).	
	✓	SARNA, et al., "Systemic administration of recombinant methionyl human interleukin-2 (Ala 125) to cancer patients: Clinical results" <i>Journal of Biological Response Modifiers</i> 8:16-24 (1989).	
	✓	SARNA, et al., "A pilot study of intralymphatic interleukin-2. II. Clinical and biological effects" <i>Journal of Biological Response Modifiers</i> 9:81-86 (1990).	
Alb	✓	SARTHOU, et al., "Prognostic value of anti- <i>Plasmodium falciparum</i> -specific immunoglobulin G3, cytokines, and their soluble receptors in west African patients with severe malaria" <i>Infect. Immun.</i> 65(8):3271-3276 (1997).	

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Sheet 13 of 15

## Complete if Known

Application Number	09/699,003
Filing Date	October 26, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	3767
Examiner Name	P. Bianco
Attorney Docket Number	LEN 101 CIP CON

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
CLP	✓	SATO, et al., "induction of bone formation in an adenoid cystic carcinoma of the maxillary sinus by adoptive immunotherapy involving intra-arterial injection of lymphokine-activated killer cells and recombinant interleukin-2 in combination with radiotherapy" <i>Journal of Biological Response Modifiers</i> 9:329-334 (1990).	
	✓	SCHAADT, et al., "Phase II study of recombinant human tumor necrosis factor in colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 9:247-250 (1990).	
	✓	SCHALL, et al., "molecular cloning and expression of a receptor for human tumor necrosis factor" <i>Cell</i> 61:361-370 (1990).	
	✓	SCHEITHAUER, et al., "Combined $\alpha$ -2C-interferon/VMCP polychemotherapy versus VMCP polychemotherapy a induction therapy in multiple myeloma: A prospective randomized trial" <i>Journal of Biological Response Modifiers</i> 8:109-115 (1989).	
	✓	SCHILLER, et al., "A phase I trial of interferon- $\alpha$ -2a plus cyclophosphamide, vincristine, prednisone, and doxorubicin" <i>Journal of Biological Response Modifiers</i> 8:252-261 (1989).	
	✓	SECKINGER, et al., "Purification and biologic characterization of a specific tumor necrosis factor $\alpha$ inhibitor" <i>J. Biol. Chem.</i> 264(20):11966-11973 (1989).	
	✓	SEIGLER, et al., "Melanoma patient antibody responses to melanoma tumor-associated antigens defined by murine monoclonal antibodies" <i>Journal of Biological Response Modifiers</i> 8:37-52 (1989).	
	✓	SHAU, et al., "A pilot study of intralymphatic interleukin-2. I. Cytotoxic and surface marker changes of peripheral blood lymphocytes" <i>Journal of Biological Response Modifiers</i> 9:71-80 (1990).	
	✓	SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy - A perspective" <i>Pharmacol. Ther.</i> 57:79-128 (1993).	
	✓	SIELING, et al., "Immunosuppressive roles for IL-10 and IL-4 in human infection" <i>J. Immunol.</i> 150(12):5501-5510 (1993).	
OM	✓	SPRIGGS, "One step ahead of the game: Viral immunomodulatory molecules" <i>Ann. Rev. Immunol.</i> 14:101-130 (1996).	

Examiner's Signature	<i>P. Bianco</i>	Date Considered	9/20/05
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		Application Number	09/699,003
		Filing Date	October 26, 2000
		First Named Inventor	M. Rigdon Lentz
		Group Art Unit	3762
		Examiner Name	P. Bianco
		Attorney Docket Number	LEN 101 CIP CON

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
<i>blb</i>	✓	STEGER, et al., "Long-term remission in a patient with erythroleukemia following interferon- $\alpha$ treatment" <i>Journal of Biological Response Modifiers</i> 8:351-354 (1989).	
	✓	STEINMETZ, et al., "Phase I study of 24-hour continuous intravenous infusion of recombinant human tumor necrosis factor" <i>Journal of Biological Response Modifiers</i> 7:417-423 (1988).	
	✓	SZNOL, et al., "A phase I study of high-dose interleukin-2 in combination with interferon $\alpha_{2b}$ " <i>Journal of Biological Response Modifiers</i> 9:529-537 (1990).	
	✓	TRIGG, et al., " $\alpha$ -interferon therapy for lymphoproliferative disorders developing in two children following bone marrow transplants" <i>Journal of Biological Response Modifiers</i> 8:603-613 (1989).	
	✓	TRINCHIERI, et al., "Cytokine cross-talk between phagocytic cells and lymphocytes: Relevance for differentiation/Activation of phagocytic cells and regulation of adaptive immunity" <i>J. Cell. Biochem.</i> 53:301-308 (1993).	
	✓	TRUMP et al., "Interferon- $\alpha$ -n1 and continuous infusion vinblastine for treatment of advanced renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:108-111 (1990).	
	✓	UMIEL, et al., "Recombinant interleukin-2-activated intracavitory lymphocytes: Phenotypic characteristics and effector function" <i>Journal of Biological Response Modifiers</i> 8:409-421 (1989).	
	✓	VON HOFF, et al., "Phase II evaluation of recombinant $\gamma$ -interferon in patients with advanced pancreatic carcinoma: A southwest oncology group study" <i>Journal of Biological Response Modifiers</i> 9:584-587 (1990).	
	✓	WALSH, et al., "Phase I study of the combination of alpha-2 interferon and cisplatin" <i>Journal of Biological Response Modifiers</i> 8:11-15 (1989).	
<i>blb</i>	✓	WEIL-HILLMAN, et al., "Transient decrease in IL-2 responsive lymphocytes 24 hours after initiation of continuous IL-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 7:424-437 (1988).	
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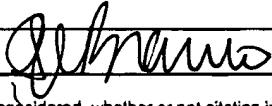
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QJM	✓	WHITEHEAD, et al., "A phase II trial of recombinant tumor necrosis factor in patients with metastatic colorectal adenocarcinoma: A southwest oncology group study" <i>Journal of Biological Response Modifiers</i> 9:588-591 (1990).	
QJM	✓	YELAVARTHI, et al., "Analysis of p60 and p80 tumor necrosis factor-alpha" <i>American Journal of Pathology</i> 143:1131-1141 (1993).	
QJM	✓	ZAMKOFF, et al., "A Phase I trial of subcutaneously administered recombinant tumor necrosis factor to patients with advanced malignancy" <i>Journal of Biological Response Modifiers</i> 8:539-552 (1989).	

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Street Address 1 of 1

<b>Complete if Known</b>	
<b>Application Number</b>	09/699,003
<b>Filing Date</b>	October 26, 2000
<b>First Named Inventor</b>	M. Riggdon Lentz
<b>Group Art Unit</b>	3762
<b>Examiner Name</b>	Patricia Bianco
<b>Attorney Docket Number</b>	LEN 101 CIP CON

**U.S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

**Examiner's  
Signature**

Belbrano

**Date Considered**

9/10/05

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<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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